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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,396	07/10/2001	Keith D. Allen	R-359	9463

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EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/903,396	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *36-41,47 and 48*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Joe Woitach
AU 1632

Continuation of 5. does NOT place the application in condition for allowance because: : 1) Those arguments that rely on the proposed amendment are moot since the amendment has not been entered. Applicant has presented various references including an NIH web site, Albert, Lewin, Crawley, Matise and Doetschman. This material had not been made of record earlier and is considered to be an exhibit. Since the exhibit of excerpted material is not solely directed to issues newly raised by the examiner in the Final rejection, it has not been considered and the arguments relying on the excerpted material have not been considered. 2) With respect to the rejection for lack of specific and substantial utility, Applicant argues that the particular transgenic mouse being claimed has specific, substantial, and therefore, well-established utility because knock-out mice, in general, can be used to define the function and role of the disrupted target gene. In response, this is not a specific and substantial use of the knock-out mouse itself, but one of the general method of making and using knock-out mice as a research tool. Determining what phenotype the mouse has, is using the mouse as an object of research. The question is what can the mouse be used for that is considered to be a specific and substantial utility, i.e. that provides immediate benefit to the public in a real world context of use. Using the claimed mouse as an object of research is not a substantial utility and does not meet the requirements of 35 USC 101, see Brenner (148 USPQ 689) at pages 659-696. 3)Applicant asserts that the claimed mice are being used commercially. In response, Applicant has provided no evidence to support this assertion. If true, there is no indication as to why the companies ordered the mouse, or what use they have for it, or whether such use is still as an object of research or whether such use constitutes a specific and substantial utility taught by the specification. 4) Applicant equates the instant fact pattern with that in Brana. The fact pattern in Brana is not similar to that of the instant invention. In Brana, the court addressed two separate issues, utility and enablement. The court held that the specification did disclose a specific and substantial use for the compound that was overlooked by the PTO, treating leukemia. The court also observed that the claimed compound was similar in structure to a prior art compound useful for treating leukemia and behaved similar to the prior art compound in art accepted assays for anti-leukemia activity, and so the specification had enabled that use. In contrast, the evidence of record shows that the physiological function of the glucocorticoid-induced receptor gene was not known. Therefore, unlike in Brana, the claimed gene or mouse cannot be linked to a disorder such as leukemia and, unlike the situation in Brana, the grounds of rejection provide ample evidence of reasons to doubt the assertions made in the specification, and that considerable experimentation would be required to confirm or deny the assertions made in the specification. Applicant has yet to directly address any of the evidence upon which the rejection is based. 5)The enablement rejection with respect to the genetic background of the claimed mice is maintained for reasons of record. The claims encompass any genetic background while the specification clearly sets forth that different backgrounds result in different phenotypes. Applicant has argued that the examiner has failed to set forth any evidence that the same phenotypic response occurs in various genetic backgrounds. Applicant presents the teachings of Bilkie Gorzo as an example where genetic background does not affect phenotypic manifestation of a genetic disruption. In response, Applicant's own specification demonstrates differences in phenotype between strains and the excerpt of Bilkie-Gorzo is replete with statements regarding the differences in performance of mice comprising the same gene disruption on different genetic backgrounds as well as differences in the effects of pharmaceuticals on the different genetic backgrounds.